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Does a Prefabricated Gentamicin-impregnated, Load-bearing Spacer Control Periprosthetic Hip Infection?

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Abstract

Introduction Treating deep infection following THA has been a challenge. While the standard treatment has remained a two-stage revision, spacer designs, incorporated antibiotics, and concentrations have varied. Since control of infection may relate to choice and concentration of antibiotics, it is important to report rates of control from various spacers.

Questions/purposes We therefore determined (1) the rate of infection control and (2) complications associated with a prefabricated, load-bearing, gentamicin-impregnated hip spacer in treating periprosthetic infections of the hip.

Methods We retrospectively reviewed 33 patients with periprosthetic THA infections treated with a prefabricated, partial load-bearing, gentamicin-impregnated hemiarthroplasty spacer. Thirty of the 33 patients underwent second stage reimplantation after a mean 15 weeks. We collected patient demographic data, laboratory values, infecting organism, size of spacer mold, antibiotic selection, complications, and infection control rates from two academic centers. Recurrent infection at last followup was determined by the presence of physical symptoms or signs or elevated serologic tests. The minimum followup was 24 months (mean, 43 months; range, 24–70 months).

Results Twenty-eight of the 30 patients who underwent reimplantation remained infection-free at last followup: one patient became reinfected with a different organism secondary to wound problems; one became reinfected with the same organism, but was restaged with the mold used in this study, reimplanted, and subsequently remained free of infection. Two of the 33 patients had persistently elevated inflammatory markers at the completion of their first stage and were restaged with this mold; both underwent reimplantation and remained free of infection at latest followup. One of the 33 patients was satisfied and ambulatory with their spacer mold. There were no major complications.

Conclusion Our data supported the use of a partial load-bearing, gentamicin-impregnated hemiarthroplasty spacer in treating deep periprosthetic THA infections.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

One of the major complications associated with THA has been deep periprosthetic infection. Despite improvements in intraoperative techniques to enhance the sterility of the procedure and the ability of preoperative prophylactic antibiotics to reduce infection rates, longer and more rigorous followup of patients has reported deep site infections at a frequency of 0.25% to 2%, depending on surveillance periods [16]. Diagnosis has typically been made using a combination of history, physical exam, and laboratory investigations, including erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels. Fluoroscopic joint aspirations have been used as an adjunct to sample the joint fluid to confirm the presence of an infection and identify the offending pathogen [4, 17]. Treating infection has consisted of nonoperative management with systemic antibiotics or surgical management [21]. Surgical options have included component retention with local irrigation and debridement with or without polyethylene liner exchange, one- or two-stage revisions, or resection arthroplasty [19, 21]. For chronic, delayed infections, most surgeons in North American have considered a two-stage revision the gold standard [3, 20], often utilizing a spacer of either partial load-bearing design [8] or an interpositional, nonload-bearing design [5, 7, 8, 20] between stages with concurrent parenteral antibiotic therapy. Partial load-bearing spacers have offered the benefits of preserving bone stock, maintaining the soft tissue envelope, and potentially improving functionality between stages [7, 8]. Interpositional spacers have allowed incorporation of higher doses of antibiotics while avoiding the pitfalls of spacer dislocation and fracture seen in the articulating group [8].

With the change in population demographics and the increasing prevalence of THA among the elderly in the years to come [11–13], more evidence is needed to guide the definitive treatment of periprosthetic infections because the incidence of this seemingly infrequent complication is expected to rise. However, there has been a lack of consensus on the type of spacer that should be implanted, as well as the antibiotic and its concentration that should be incorporated into these spacers. The infection control rates that have been associated with the various types of available spacers and their indications need to be defined in order to help maximize rates of infection control, while minimizing cost and hospitalization lengths [10].

We therefore determined (1) the rate of infection control and (2) complications associated with a prefabricated, partial load-bearing, gentamicin-impregnated hemiarthroplasty hip spacer in treating periprosthetic infections of the hip.

Patients and Methods

We retrospectively identified all 33 patients who underwent two-stage revision THA for infection with the use of the hemiarthroplasty Spacer G (Tecres™ SpA Sommacampagna, Verona, Italy, distributed by Exactech, Gainesville, Florida, USA) in two tertiary care centers under the care of five experienced arthroplasty surgeons (JRD, JLH, RWM, RBB, DNN) between May 2006 and July 2010. We initially identified patients via billing codes for revision arthroplasty, followed by a chart review to identify if this specific prosthesis was used in their two-stage revision. All 33 patients who underwent a staged revision with the aforementioned prosthesis were included in our study. We excluded one patient who had substantial acetabular bone deficiency superiorly and medially, due to concerns regarding superior or intrapelvic dislocation of the spacer. The 33 patients comprised of 22 men and 11 women, with an average age of 67 years (range, 51–86 years). No patients were lost to followup. The minimum followup was 24 months (mean, 43 months; range, 24–70 months).

The surgical technique used in most cases consisted of a direct lateral Hardinge approach. One posterior Kocher-Langenbeck approach was used in a patient who had this incision used for their primary joint arthroplasty. Prior to implant removal, we sent three joint fluid cultures for testing upon entering the joint capsule. Additionally, we sent tissue membrane samples for culture from both the acetabulum and femoral canal. Eighteen patients required an extended trochanteric osteotomy (ETO) to assist in removal of their primary prosthesis. After removal of implants, surgeons conducted a thorough soft tissue débridement, followed by implantation of the Tecres™ Spacer G hemiarthroplasty. Each spacer was coated with a proximal cement mantle to accommodate for the relative metaphyseal-diaphyseal mismatch with this spacer design. The cement typically contained 3.6 grams of tobramycin and 3 grams of vancomycin, and was dyed with methylene blue for easier identification and subsequent removal at time of their definitive second stage reimplantation. The spacers ranged in size from 46 to 60 mm, which corresponded to the patient's femoral head diameter. Twenty-two of the 33 spacers were extra-long, which the surgeons favored in order to bypass the osteotomy site and improve stability in cases where an ETO was performed.

Postoperatively, we observed the cultures for pathogens. While Staphylococcus aureus infections were the most prevalent species identified at both sites, several different organisms were identified from preoperative aspirates or cultures taken at the first stage procedure (Table 1). Additionally, we checked sensitivities and appropriately tailored antibiotics according to these results. We treated

Table 1. Organisms identified from preoperative aspirates or cultures taken at the first stage procedure

Organism	Number of cultures
University of Western Ontario (London Health Sciences Center, University Campus)	
Staphylococcus aureus	4
MRSA	4
None identified	4
Enterococcus faecalis	2
Staphylococcus epidermis	2
Haemophilus influenza	1
Propionobacter	1
Peptostreptococcus	1
University of Toronto (Toronto Western Hospital)	
Coagulase negative Staphylococcus	5
Staphylococcus aureus	3
MRSA	1
None identified	1
Enterococcus faecalis	1
Group B Streptococcus	1
Gram positive cocci	1
Peptostreptococcus	1

MRSA = methicillin-resistant Staphylococcus aureus.

culture negative cases with cefazolin. Antibiotics were initiated and delivered parenterally for a minimum of 6 weeks via a peripherally inserted central catheter. After completion of this period, we repeated ESR and CRP levels to establish a baseline, and then followed patients during an antibiotic holiday, where we rechecked ESR and CRP levels after 6 weeks to prepare for reimplantation. We did not routinely obtain aspirates, but if we had clinical suspicions because of elevated serologic testing or clinical findings, we obtained fluoroscopic aspirates.

Physiotherapists worked with patients in the immediate postoperative period to assist with mobilization, with 50% weightbearing on their partial load-bearing spacer to facilitate discharge home.

Once satisfied that the infection had been controlled, usually based on their clinical assessment and repeat lab investigations with an ESR below 30 mm per hour and CRP below 10 mg/L (similar to the newly established guidelines by Della Valle et al. [17]), surgeons proceeded with the second stage reimplantation procedure. Preoperative joint aspiration was performed in some patients as an adjunct to the above, or if there was any clinical or laboratory suspicion of infection. Surgeons utilized the same surgical approach as in the initial procedure to expose and extract the antibiotic spacers and antibiotic cement. Again, surgeons performed a thorough soft tissue debridement, followed by implantation of their definitive components. Patients retained their spacers for an average of 15 weeks (range, 11–19 weeks), with concurrent parenteral antibiotic therapy for a minimum of 6 weeks. Patients continued the antibiotics following the second stage until the intraoperative cultures were confirmed to be negative (average, 5 days). Following second stage revision, patients were routinely kept on protected weightbearing for 3 months (10% for 6 weeks, then 50% for 6 weeks).

After their initial postoperative course and discharge from hospital, patients underwent clinical followup at 6 weeks, 3, 6, and 12 months, and then annually with radiographs. We monitored patients for physical symptoms or signs of recurrent infection. We did not regularly perform serologic tests, but rather reserved them for patients with symptoms or signs of infection at the time of clinical assessment. We considered the infection to be controlled if there was an absence of any clinical signs or if the patient had an ESR less than 30 mm/hour and CRP less than 10 mg/L. We conducted an electronic and paper-based chart review to identify several variables relating to their total joint infection and revision process. Specifically, we recorded data on patient demographics, laboratory investigations, size of the spacer implanted, organism identified at first stage, time to control of infection, outcomes, and any associated spacer-related complications. There were no missing data.

Results

At last followup, infection was controlled after a single two-staged procedure in 28 of 33 (85%) patients. Two patients had persistently elevated inflammatory markers after the first stage, and subsequently underwent restaging with repeat débridement and spacer exchange at the date of their intended second stage. Both had interim control of their infections and went on to reimplantation at an average of 19 weeks. Both of these patients had an infection with methicillin-resistant *Staphylococcus aureus* (MRSA). Subsequent reimplantation controlled the primary infection. Two additional patients had reinfection after undergoing reimplantation at their second stage procedure: one became infected with the same bacteria that caused their initial infection, while the other became infected with a different bacterium. Both of these patients underwent a repeat two-stage revision with the same spacer mold, and, at latest followup, had control of their infections. The final patient elected to forego reimplantation. This patient had numerous medical comorbidities, was deemed high-risk for further operations, and had a functional, painless limb, and thus elected to retain their prosthesis. In the end, infection control was ultimately achieved in 32 of 33 (97%) patients.

One patient had what we considered a spacer-related complication. This patient suffered a periprosthetic femur

fracture prior to their initial infection. At the time of the first-stage revision and insertion of their antibiotic spacer, the fracture had only partly healed. Postoperative restrictions recommended the patient remain nonweightbearing on the affected side; however, the patient did not abide by these restrictions and subsequently bent the spacer in situ. Further complications, unrelated to spacer use, occurred in four patients. Three of these consisted of undisplaced femoral shaft fractures occurring at the time of removal of their primary prosthesis and required no further form of fixation. The other case involved a patient who had instability following the completion of their second stage and went on to have multiple dislocations and eventual insertion of a constrained polyethylene liner.

Discussion

Deep periprosthetic infections have been a difficult problem following THA. As outlined, there have been many different treatment options depending on the type of infection present. The gold standard for a chronic, delayed presentation infection has remained a two-stage revision procedure with an antibiotic spacer. While many studies have reported infection control with a two-stage procedure [5, 18–22], they provided no clear attribution to the effect of the various spacers used in these studies. Antibiotic concentration has also been controversial. While selection has been limited to thermostable antibiotics due to the exothermic nature of polymethylmethacrylate (PMMA) formation, the effective concentration for control of infection has yet to be determined [3]. Control of infection may relate to the design of the spacer (eg, choice and concentration of antibiotics). We therefore determined (1) the rate of infection control and (2) complications associated with this particular prefabricated, load-bearing, gentamicin-impregnated hemiarthroplasty hip spacer in treating periprosthetic infections of the hip.

There were some limitations to our study. First, the sample size was limited to 33 patients; however, given the relative infrequency of infections, our sample size was consistent with other reported figures in the literature [5, 6, 18]. Second, our followup was limited to a minimum of 24 months as a result of the participating centers having adopted this particular prosthesis only in recent years. Preliminary reports, largely from the work of Sanchez-Sotelo et al. [19], have shown a minor increase in reinfection rates with prolonged followup relative to preliminary reports [14, 15], and future studies should include longitudinal followup of these particular patients. Third, we had no control group of other spacers and depended upon literature comparisons (Table 2). Given the relative infrequency of these infections and the current rates of infection control, a large multicenter study would be required for a controlled study; therefore, until one is available, we will need to depend upon single cohort studies to assess new technologies for treating periprosthetic hip infections.

We were able to control infection after a two-stage procedure in 28 of 33 (85%) patients. This was comparable to ranges in the literature from 83% to 95% [5, 6, 14, 15, 18–20, 22]. In one of the few long-term followup studies, Sanchez-Sotelo et al. [19] performed a retrospective review of 169 patients undergoing two-stage revision THA for infection and investigated the rates of both mechanical failure and reinfection. They had a success rate of 88% in preventing reinfection at 10-year followup. Notably, the majority of their patients underwent resection arthroplasty during the first stage and did not receive a spacer for the duration between the first and second stages. Similarly, with one of the highest success rates (95%), Toulsen et al. [20] reported on the outcomes for infected periprosthetic THA undergoing two-stage revisions with

Table 2. Comparative studies in the treatment of deep periprosthetic hip infections

Study	Cases	Infection control	Average followup (years)	Spacer-related complication rate (%)
Sanchez-Sotello et al. [19]	169	87.5%	10	NR
Toulson et al. [20]	84	95%	3	NR
Durbhakula et al. [6]	24	92%	2.5	NR
Wentworth et al. [22]	97	91.8%	NR	6.1
Pignatti et al. [18]	41	95%	5.3	4.9
Diwanji et al. [5]	9	88.9%	3.6	NR
Lieberman et al. [14]	32	91%	3.3	NR
Masri et al. [15]	29	89.7%	2 (minimum)	NR
Current study	33	85%	3.5	3.0

NR = not reported.

antibiotic-impregnated articulating spacers. They followed 84 patients for an average of 3 years. While only four patients went on to reinfection with their primary pathogen, an additional six patients went on to reinfection with a different organism, but were not included in the reinfection group. This may have represented a failure to recognize polymicrobial infections early on in the treatment regimen, later falsely attributed to representing a new infection. Wentworth et al. [22] also investigated the success rate of infection control with an articulating spacer. They followed 116 patients after two-stage revision, utilizing the novel Prostalac® (DePuy, Warsaw, IN, USA) spacer, a prosthesis that involved a femoral component that was constructed intraoperatively using a cobalt-chrome core with a mold that allowed addition of antibiotic-laden PMMA to the femoral stem. This design allowed variable selection and dosage of the antibiotic, conferring the benefit of a more tailored antibiotic treatment. This stem was then coupled with a 32-mm modular cobalt-chrome head that articulated with an acetabular component that was a polyethylene snap-fit liner. Their success rate was 83%. One similar study using the Tecres® Spacer G hemiarthroplasty spacer exists. Pignatti et al. [18] followed 41 patients undergoing two-stage revisions for infected THA, with 36 of those patients undergoing revision with the Tecres® Spacer G. Although nine patients required repeat staging, at the completion of their study, they reported a control rate of 100%. Their and our results supported the use of this spacer for treating periprosthetic infections.

While the Tecres® Spacer G was a partial load-bearing spacer; nonload-bearing interpositional spacers have remained in use in many centers. Although there has been no demonstrated difference regarding infection control, some surgeons have favored partial load-bearing spacers, with conferred benefits of improved joint motion [15]. In the knee, partial load-bearing articulating spacers have allowed easier reimplantation during the second stage, and decreased bone loss between stages [7]. Conversely, interpositional spacers have offered higher local delivery of antibiotics, but were associated with soft tissue contractures, limited range of motion, and increased bone loss [3, 7, 8]. In the hip, partial load-bearing spacers have been associated with an alternate set of complications, as they had higher rates of dislocation and fracture of the spacer itself [8]. The Tecres® Spacer G was a gentamicin-impregnated PMMA bone-cement molded to a stainless-steel reinforcing core. It was rigid due to the stainless-steel endoskeleton and was prefabricated, making it easy to implant, and reliable in terms of construct strength and antibiotic concentration.

One study questioned whether the dose of gentamicin found in these prefabricated spacers could reach bactericidal levels in vivo [8]. As a result, some proposed these spacers were unfit for treating chronic periprosthetic joint infections [1]. In vitro studies looking at elution characteristics of gentamicin from these spacers showed an initial high release profile, which then tapered, but persisted for many months [2, 9]. Further modifications of these study designs included drilling holes in the proximal end of the spacer and adding a vancomycin-impregnated cement mantle to the prefabricated spacer design. This seemed to improve the release of gentamicin and conferred the added benefit of additional antibiotic coverage. While it is difficult to correlate in vitro studies to in vivo studies, another study [2] sampled joint fluid to assess in vivo release of antibiotics and found sample fluids containing antibiotic concentrations well above the minimum inhibitory concentration for the majority of common orthopaedic pathogens with use of these prefabricated spacers. At both our institutions, a proximal cement mantle containing vancomycin and tobramycin was added to improve antibiotic release, presumably to bactericidal levels, and accommodate for any metaphyseal-diaphyseal mismatch of the spacer design.

In conclusion, in the setting of a two-stage revision, coupled with thorough soft-tissue débridement and an extended course of parenteral antibiotics, our data supported the use of a partial load-bearing, gentamicin-impregnated, hemiarthroplasty spacer for treating deep periprosthetic THA infections. We found infection control rates similar to that of several studies in the literature, while also offering a low complication rate associated with the use of this spacer. Further randomized studies are required to show the potential beneficial effect associated with this relatively new implant. Longitudinal studies continuing to follow the outcomes associated with this spacer are also required to further support its use. Additional studies investigating its use in MRSA infections are required to better delineate timelines for two-stage procedures using this spacer in treating resistant bacteria.

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